

[00105] WHAT IS CLAIMED IS:

1. A communication device for communicating with a computing element, the computing element executing a closed-loop algorithm for controlling a delivery rate of an infusion formulation by an infusion pump in response to a sensed biological state, the communication device comprising:

- an outer housing;
- a power source;
- a plurality of user-selectable operators attached to the housing, each of the plurality of user-selectable operators being selectable for initiating communication of signals to the computing element, the signals representing events affecting the sensed biological state; and
- a transmission device for transmitting the signals to the computing element;

wherein the closed-loop algorithm processes the signals received by the computing element and adjusts the delivery rate of an infusion formulation in accordance with pre-programmed information relating to the events represented by the signals.

2. The communication device recited in claim 1, wherein the infusion formulation comprises an insulin formulation.

3. The communication device recited in claim 1, wherein the sensed biological state comprises a sensed glucose level.

4. The communication device recited in claim 1, wherein the events affecting the sensed biological state comprise at least one of a meal event, a sleep event, a medication event, a stress event, and an exercise event.

5. The communication device recited in claim 1, wherein the transmission device is a radio frequency transmitter.

6. The communication device recited in claim 1, further comprising a plurality of user-selectable operators attached to the housing, each of the plurality of user-selectable operators being selectable for communicating signals to the computing element, the signals representing event rankings associated with respective ones of the events, the event rankings affecting the sensed biological state.

7. The communication device recited in claim 6, wherein the event rankings comprise at least one of a degree, quantity, and measure of the respective ones of the events.

8. The communication device recited in claim 6, wherein the event rankings comprise at least one of "light," "moderate," "heavy," "short," "long," "low," and "high."

9. The communication device recited in claim 1, wherein the infusion pump is an implantable infusion pump.

10. A communication device for communicating with a computing element, the computing element executing a closed-loop algorithm for controlling a delivery rate of an infusion formulation by an infusion pump in response to a sensed biological state, the communication device comprising:

- an outer housing;
- a power source;
- a display for displaying events and event rankings affecting the sensed biological state;

a plurality of user-selectable operators for selecting particular events and event rankings and for initiating communication of signals to the computing element, the signals representing the events and the event rankings; and

a transmission device for transmitting the signals to the computing element;

wherein the closed-loop algorithm executed by the computing element processes the signals to determine an adjustment in the infusion formulation delivery rate based on pre-programmed information about the events and event rankings represented by the received signals.

11. The communication device recited in claim 10, wherein the infusion formulation comprises an insulin formulation.

12. The communication device recited in claim 10, wherein the sensed biological state comprises a sensed glucose level.

13. The communication device recited in claim 10, wherein the events affecting the sensed biological state comprise at least one of a meal event, a sleep event, a medication event, a stress event, and an exercise event.

14. The communication device recited in claim 10, wherein the event rankings comprise at least one of "light," "moderate," "heavy," "short," "long," "low," and "high."

15. The communication device recited in claim 10, wherein the event rankings comprise dietary information about a meal event.

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16. The communication device recited in claim 15, wherein the dietary information about a meal event comprises at least one of carbohydrate content, fat content, and protein content.

17. The communication device recited in claim 15, wherein dietary information about a meal event comprises food type and serving size.

18. An infusion pump system for use in delivery of an infusion formulation, the system comprising:

- a pump for delivering measured doses of an infusion formulation;
- a sensing device for sensing a biological state;
- a computing element communicating with the sensing device, the computing element being programmed to receive information about the sensed biological state from the sensing device and to regulate the delivery of the infusion formulation in accordance with the received information; and
- a communication device communicating with the computing element, the communication device for communicating a user-initiated event signal to the computing element, the user-initiated event signal being representative of an event affecting the sensed biological state;

wherein the computing element is further programmed to receive the user-initiated event signal and initiate a variation in the delivery of the infusion formulation in accordance with the received user-initiated signal.

19. The infusion pump system recited in claim 18, wherein the variation in the delivery of the infusion formulation is substantially contemporaneous with the receipt of the user-initiated signal.

20. The infusion pump system recited in claim 18, wherein the sensing device for sensing the biological state comprises a sensing device for sensing a glucose level.

21. The infusion pump system recited in claim 18, wherein the computing element is programmed to regulate the delivery of an insulin formulation.

22. The infusion pump system recited in claim 21, wherein the computing element is programmed to initiate an event-based variation in the delivery of the insulin formulation which comprises at least one of an increase in an amount of the delivered insulin formulation and a decrease in an amount of the delivered insulin formulation.

23. The infusion pump system recited in claim 21, wherein the computing element is further programmed to initiate an event-based variation in the delivery of the insulin formulation which comprises a bolus delivery of the insulin formulation.

24. The infusion pump system recited in claim 18, wherein the user-initiated event signal is representative of at least one of a meal event, an exercise event, a stress event, a sleep event, and a medication event.

25. The infusion pump system recited in claim 24, wherein the communication device further communicates a user-initiated event ranking signal representative of an event ranking.

26. The infusion pump system recited in claim 18, wherein the communication device comprises a plurality of user-selectable operators corresponding to respective ones of a plurality of events, the user-selectable

operators being selectable for communicating to the computing element the user-initiated signal.

27. The infusion pump system recited in claim 18, wherein the communication device comprises a plurality of user-selectable operators corresponding to respective ones of a plurality of event rankings.

28. The infusion pump system recited in claim 18, wherein the communication device comprises a display for displaying events and event rankings affecting the sensed biological state.

29. The infusion pump system recited in claim 28, wherein the communication device further comprises a plurality of user-selectable operators for selecting particular events and event rankings on the display and for initiating communication of the signals to the computing element, the signals representing the events and the event rankings.

30. The infusion pump system recited in claim 18, wherein the computing element is further programmed to perform diagnostics in order to verify that the user initiated event signal is consistent with a detected change in the sensed biological state.

31. The infusion pump system recited in claim 30, wherein the user is alerted when the user initiated event signal is not consistent with the detected change in the sensed biological state.

32. The infusion pump system recited in claim 30, wherein the closed-loop algorithm ceases an automatic control of the infusion pump and returns to a manual operation of the infusion pump when the user initiated

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event signal is not consistent with the detected change in the sensed biological state.

33. The infusion pump system recited in claim 25, wherein the computing element is further programmed to dynamically adjust the amount of infusion formulation delivered based on a first user-initiated event ranking signal when a second user-initiated event ranking signal is received by the computing element.

34. The infusion pump system recited in claim 18, wherein the computing element is further programmed to maintain a history of user-initiated event signals.

35. The infusion pump system recited in claim 34, wherein the history is accessible to at least one of the user and the user's physician.

36. The infusion pump system recited in claim 18, wherein the pump is an implantable pump.

37. A process for providing safety limits on the delivery of infusion formulation by an infusion pump system in response to a sensed biological state, comprising:

monitoring a biological state;

providing information about the biological state to a computing element, the computing element being programmed to regulate the delivery of the infusion formulation in accordance with the information; and

communicating a user-initiated event signal to the computing element, the user-initiated event signal being representative of an event affecting the biological state;

wherein the computing element is further programmed to receive the user-initiated event signal and initiate a variation in the delivery of the infusion formulation in accordance with the received user-initiated signal.

38. The process recited in claim 37, wherein the biological state comprises a glucose level.

39. The process recited in claim 37, wherein the infusion formulation comprises an insulin formulation.

40. The process recited in claim 37, wherein the event affecting the biological state comprises at least one of a meal event, an exercise event, a stress event, a sleep event, and a medication event.

41. The process recited in claim 37, further comprising communicating a user-initiated event ranking signal to the computing element, the user-initiated event ranking signal being representative of an event ranking affecting the biological state.

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